Trade Facts

Office of the United States Trade Representative ***www.ustr.gov***
July 19, 2004

U.S.-Morocco Free Trade Agreement: Access to Medicines

- **Under global trade rules and U.S. bilateral trade agreements, countries have access to medicines in their fight against HIV-AIDS and other epidemics.**
    - The U.S. played a key role in the Doha WTO Ministerial (Nov. 2001) reaffirmation that global trade rules allow countries to decide what constitutes a health emergency and to issue compulsory licenses to produce drugs needed to fight epidemics.
    - In August of 2003, the U.S. led the work towards a WTO consensus that allows poor countries without domestic drug production capacity to issue compulsory licenses to import drugs needed to combat diseases such as HIV/AIDS, malaria, tuberculosis and other infectious epidemics.

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- **The Morocco FTA will not affect that country's ability to take measures necessary to protect public health or to use the WTO solution to import drugs.**
    - The Morocco FTA expressly states that nothing in the IP chapter affects that country's ability to take measures necessary to protect public health.
        - Specifically, the United States and Morocco confirmed their understanding that the IP chapter does not "affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency."
    - The FTA also expressly states that it will not prevent effective utilization of last year's WTO consensus allowing developing countries that lack pharmaceutical manufacturing capacity to import drugs under compulsory licenses.
- **Stronger patent and data protection increases the willingness of companies to release innovative drugs in free trade partners' markets, potentially increasing, rather than decreasing, the availability of medicines.**
        - The U.S.-Jordan FTA, signed in 2000, contained an intellectual property chapter that covered data protection.

- Since 2000, there have been 32 new innovative product launches in Jordan, a substantial increase in the rate of approval of innovative drugs, helping facilitate Jordanian consumers' access to medicines. .

- Since enactment of the FTA, the Jordanian drug industry has begun to develop its own innovative medicines. This is an example of how strong intellectual property protection can bring substantial benefits to developing countries.

- **Provisions governing importation of patented products reflect <u>existing</u> Moroccan and U.S. law, and do not require Morocco to do anything it does not already do.**

  - Morocco decided in 2000, <u>well before the FTA negotiations</u>, not to permit parallel imports of patented products.

  - The FTA simply <u>reflects current law in the U.S. and Morocco</u>. Both countries already provide patent owners with an exclusive right to import patented products, including pharmaceuticals but also all other types of patented products.

  - Indeed, many innovative industries and their employees in the United States -- high tech, chemicals, agricultural inputs, engineering and manufacturing -- benefit from this long-standing protection in U.S. patent law.

  - The fact that the FTA reflects principles already present in both Parties' laws does not in any way lessen our commitment to the Doha Declaration. In fact, in previous FTA negotiations with developing countries that do not have parallel import restrictions in their domestic law (e.g., Central America, Chile, and Bahrain), the final negotiated texts do not contain provisions on parallel importation.

> *[USTR shall seek to ensure] "that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law."*
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> *-- Trade Act of 2002, Section 2102(b)(4)*

- **"Data Protection" provisions in the Morocco FTA are part of the broad framework to protect innovation.**

  - Before a drug can be sold, the drug must first be approved by a regulatory agency, such as the FDA in the United States, as being safe and effective.

  - Regulatory approval is a long and costly process designed to ensure the safety and effectiveness of the product.

    - The FDA requires extensive testing before it approves a drug.
    - Clinical trials take an average of 7-10 years.
    - The process is very risky. On average, only 20-30% of drugs that reach the last phase of testing actually receive approval.

  - The data that results from these tests is extremely valuable.

- **Protecting such data is consistent with longstanding U.S. and international practice.**

    - Global trade rules (the Trade-Related Aspects of Intellectual Property, or TRIPS) already require protection for data submitted for marketing approval. Article 39.3 of TRIPS requires countries to protect such data against "unfair commercial use."

    - Data protection provisions were also included in many past trade agreements including the U.S.-Jordan FTA and the U.S.-Vietnam Bilateral Trade Agreement – both negotiated by the previous Administration – as well as in the NAFTA and all recent FTAs, including the U.S.-Singapore FTA and the U.S.-Chile FTA, and many bilateral intellectual property agreements.

    - TRIPS does not specify a period of time for protection - the Morocco FTA text is based on the standard for protection in the U.S. – five years from the date of marketing approval. There is no circumstance in which the FTA requires that an innovator receive a data protection period longer than five years for new chemical entities.

    - Competitors can apply for approval at any time using their own data. After the period of protection is over, under U.S. law, other producers can apply for marketing approval by relying on the innovator's data.

    - Terms of protection vary around the world. Virtually every OECD country provides data protection. While the US protects data for 5 years, the EU protects data for 6-10 years.

    - Data protection provides an incentive to bring innovative drugs to developing countries, and after five years, test data used to certify an innovative drug can be used to approve a generic version.